



bioMérieux Receives FDA Clearance for Expanded Use of VIDAS® B•R•A•H•M•S PCT™ Test for Managing Sepsis Patients with Elevated Risk of Mortality

Tracking PCT – a biomarker for bacterial infections – over time provides strong indication of likely mortality, enabling physicians to personalize care for high-risk patients

Marcy l'Étoile (France) - July 1st, 2016 – bioMérieux, a world leader in the field of *in vitro* diagnostics, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to expand the use of the VIDAS® B•R•A•H•M•S PCT™ (Procalcitonin) assay using the change in PCT levels over time to aid in the management of sepsis patients after the initial diagnosis. Based on a recent study, monitoring PCT levels over 4 days (96 hours) can help doctors determine which septic patients are at the greatest risk of death, enabling them to adjust or intensify the medical care for those patients.

As a pioneer dedicated to improving patient safety and infection control practices, bioMérieux was the first company to launch an automated test measuring PCT in the U.S.. Today, the VIDAS® B•R•A•H•M•S PCT™ test is the market leader for sepsis prognosis. PCT was originally cleared for use in the first day following admission to an intensive care unit (ICU), and this expanded claim demonstrates the usefulness of PCT levels which are monitored serially over 96 hours.

Monitoring serial PCT levels over 96 hours, along with ongoing clinical assessment and other laboratory tests, will provide additional information to the clinician to help with a more robust prognosis and management of patients with sepsis and septic shock. This combination of tools and data will enable physicians to assess the risk of progression and ultimately the risk of mortality in the septic patient. Armed with this vital prognostic information, physicians can more appropriately manage and aggressively support and treat those with elevated risk.

“In many patients, it can be very difficult to diagnose sepsis up until the moment of obvious shock,” said Devendra Amin, MD, FCCM, intensive care physician and medical director of Critical Care Services at Morton Plant Hospital in Clearwater, FL. *“The expanded indication for PCT will allow us to obtain vital information prior to the admission to the ICU and will give us vital information about the patient’s prognosis, risk of mortality, response to treatment and likelihood of survival.”*

As part of the FDA filing, bioMérieux submitted equivalence results of the Thermo Fisher Scientific’s Procalcitonin Monitoring SEpsis Study (MOSES), which tracked PCT levels of patients with severe sepsis or septic shock. Patients whose PCT levels decreased by 80 percent or more during the 96 hour timeframe of the study had a significantly lower risk of 28-day mortality compared to those whose PCT measurements decreased less than 80 percent over 96 hours.

“The study demonstrates that for patients diagnosed with sepsis or septic shock, failure of blood concentrations of PCT to decrease over 96 hours is a strong predictor of mortality over and above clinical indicators,” said Mark Miller, Chief Medical Officer at bioMérieux. *“Measuring PCT at clinical presentation and serially over 4 days will provide clinicians with high medical value information to help them identify patients who are at greatest risk of mortality and ultimately can result in improved, more targeted and intensified patient care and better medical outcomes”.*

About Sepsis

Sepsis is a life-threatening organ dysfunction caused by an excessive host immune response to a serious infection. According to the Centers for Disease Control and Prevention (CDC), 1.6 million Americans suffered from sepsis in 2011, of which about 260,000 did not survive¹. Sepsis is currently the most expensive reason for hospitalization in the U.S. where spending reached \$20 billion dollars on hospital care for sepsis patients in 2011².

PCT can play a critical role in addressing this clinical challenge and has become a key component of successful sepsis protocols across the U.S. and Europe. PCT levels increase precipitously in patients with severe bacterial infection. PCT is therefore an extremely important biomarker enabling specific differentiation between a severe bacterial infection and other causes of inflammatory reactions. The VIDAS[®] B•R•A•H•M•S PCT™ test generates results in 20 minutes on the bioMérieux VIDAS[®] range of small and rapid bench-top instruments that can be placed close to patients for quick results. Clinicians who would like to learn more about PCT are encouraged to visit: www.biomerieux-diagnostics.com/sepsis-0

bioMérieux has long been committed to the fight against sepsis and provides customers with solutions all along the sepsis management pathway: rapid diagnostic solutions as well as tests that help clinicians choose the appropriate antibiotic treatment for sepsis patients.

About bioMérieux

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for more than 50 years, bioMérieux is present in more than 150 countries through 42 subsidiaries and a large network of distributors. In 2015, revenues reached €1,965 million with 90% of sales outside of France.

bioMérieux provides diagnostic solutions (reagents, instruments, software) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.

bioMérieux is listed on the Euronext Paris market (Symbol: BIM – ISIN: FR0010096479).

Corporate website: www.biomerieux.com

Investor website: www.biomerieux-finance.com

CONTACTS

Investor Relations

bioMérieux

Sylvain Morgeau

Tel.: + 33 (0)4 78 87 22 37

investor.relations@biomerieux.com

Media Relations

bioMérieux

Aurore Sergeant

Tel. : + 33 4 78 87 54 75

media@biomerieux.com

Tim Baker

Tel: +1 216-407-5354

timothy.baker@biomerieux.com

Image Sept

Laurence Heilbronn

Tel. : + 33 1 53 70 74 64

lheilbronn@image7.fr

Claire Doligez

Tel. : + 33 1 53 70 74 48

cdoligez@image7.fr

¹ Elixhauser A., & al. Sepsis in U.S. Hospitals, 2009. HCUP Statistical Brief #122, Oct. 2011

² Pfunter & al. Costs for Hospital Stays in the United States. HCUP Statistical Brief #168